STATEMENT OF

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Thank you once again for the opportunity to share the Food and Drug Administration's (FDA's) views regarding our common goal of protecting patients by further enhancing the safety and security of our nation's drug supply. We view the critical task of combating counterfeit drug as a shared Federal/State endeavor—along with supply chain stakeholders---and I reiterate FDA's support for California's efforts in this mission.

At your January 23, 2008, meeting, I shared with you FDA's views regarding the status of electronic pedigree (e-pedigree) and track and trace in the US drug supply chain, so I will not repeat those remarks today. Instead, I would like to update you on some new developments related to identification, validation, authentication, and tracking and tracing of prescription drugs.

As I mentioned at the January meeting, in September 2007, Congress gave FDA new tools to effectuate electronic track and trace and e-pedigree across the drug supply chain under Section 913 of the Food and Drug Administration Amendments Act of 2007 (FDAAA). This section directs FDA to:

- 505D(b)(1): "prioritize and develop standards for the identification, validation, authentication, and tracking and tracing of prescription drugs."
    - This shall be done in consultation with manufacturers, distributors, pharmacies, other supply chain stakeholders, Department of Justice, Department of Homeland Security, Department of Commerce, and other appropriate State and Federal Agencies.
- 505D(b)(2): "develop a standard numerical identifier…to be applied to a prescription drug at the point of manufacturing and repackaging… at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug.
    - The standards shall be harmonized with international consensus standards to the extent practicable.

    - The numerical identifier applied by a repackager shall be linked to the numerical identifier applied at the point of manufacturing.
    - Develop these standards no later than March 2010.
- 505D(b)(3): The standards developed "shall address promising technologies, which may include (A) radiofrequency identification technology, (B) nanotechnology, (C) encryption technology; and other track-and-trace or authentication technologies.

On March 20, 2008, FDA published two notices in the Federal Register requesting comments and information related to new 505D of the Act. This data call is the first step in developing standards. We have set up 2 separate dockets ---one for standards and one for technology information—for efficiency and separation of the information for review purposes.

The first notice focuses on standards development. We are seeking information from drug manufacturers, distributors, pharmacies, foreign regulators, standards organizations, other Federal agencies, and other interested stakeholders. It is FDA's preference that these standards be the result of existing private and public sector collaborative standards processes. We have published a series of questions to more closely focus the responses. We intend to use the responses to determine the state of the standards development in these areas and determine how aggressively it may move forward. Recognizing the importance of uniform standards as well as the need for updating over time, FDA would consider adopting such standards through a guidance process as quickly as possible.

I will not list all the questions, but here are some examples of the type of information that we are seeking:

1) Related to the standard numerical identifier: Should it contain recognizable characteristics (e.g. National drug code number) or be random codes? How can parties in the supply chain ensure that numbers are unique and not duplicated? Should the number include the lot number and/or batch number?

2) Related to all the standards: Do standards currently exist? If so, please describe and comment on their application and use? To what extent do these standards reflect stakeholder consensus? Should this be the standard adopted by FDA? If not, is there some aspect that could be changed to make it acceptable as the FDA standards? Has it been adopted by other countries? If standards are in development, who is developing them and what is the timeline? What are the elements, provisions, and particular considerations that should be included in the standard? Are there any technical or information technology concerns? Comment on implementation in the U.S. drug supply chain, including but not limited to, feasibility, costs, timeline, interoperability, and information technology, and data storage.

3) Related to the prioritization of the standards: Should certain standards be developed and implemented before others? Should certain standards be developed and implemented concurrently?

The second notice focuses on technology. We are aware that significant progress has been made and new technologies are emerging for the identification, validation, authentication, and tracking and tracing of prescription drugs. In order to address "promising technologies" as outlined in the new provisions of the Act, we are seeking information from technology vendors and others, via the Federal Register notice, rather than meet individually with companies.

Examples of questions related to information technology include:

1) What are the RFID technologies, encryption technologies, and nanotechnologies, or other technologies that are relevant?
2) For these technologies, comment on their strengths and limitations for identification, validation, authentication, and tracking and tracing, costs of implementation and use, feasibility for widespread use, interoperability with other technologies, and what standards are necessary for supply chain use of the specific technology.

Comments for both of these notices are due by May 19, 2008. The notices, including the full list of questions and instructions on how to submit comments can be found at www.fda.gov/counterfeit.

Although these are the first steps in developing the Part 505D standards, this should not deter California's expeditious progress toward widespread implementation of serialization, electronic pedigree, and electronic track and trace in the drug supply chain. Let me close by saying again that we support California's efforts in implementing the requirements. There has been hard work and much thought to date in the standards arena associated with the drug supply chain. We are hopeful stakeholders will come together and rise to FDA's recent efforts so we can move quickly to reach our shared goals of a safer and secure drug supply chain.